K002109

Bio Med Sciences, Inc.

1111 Hamilton Street ♦ Allentown, PA 18101
Phone: (610) 432-8220 FAX: (610) 432-8240
Toll Free in U.S.: 1-800-25-SILON (1-800-257-4566)
http://www.silon.com

AUG 31 2000

XIII. 510(k) SUMMARY
Oleeva Foam

PRODUCT DESCRIPTION

Silicone sheeting has been shown to improve the cosmetic and functional aspects of dermal scars resulting from injury. Silicone sheeting has also been shown to prevent scars from forming after traumatic or surgical injury. There are a number of silicone sheeting products on the market all of which function in a similar fashion. The Applicant presently markets a family of silicone-based products for the management of hypertrophic scars and keloids. The new product adds a foam layer to silicone sheeting to provide a cushioning effect when worn under tight garments or rigid splints. The new product does not introduce any new concepts in silicone scar management but merely provides additional usage features.

The applicant intends to provide this device in a non-sterile sealed package for either healthcare professional or consumer "over-the-counter" use.

INDICATIONS FOR USE

Oleeva Foam is indicated for the management of hypertrophic scars and keloids. Oleeva Foam may be useful as a prophylaxis after surgical or traumatic dermal injury to aid in the prevention of hypertrophic scars and keloids.

SUBSTANTIAL EQUIVALENCE

The new product is substantially equivalent to the existing products manufactured and designed by Bio Med Sciences:

- Silon-SES
- Oleeva Clear
- Oleeva Fabric

BIOCOMPATIBILTY SUMMARY

Oleeva™ Foam meets the requirements of the following biocompatibility tests:

Test	Results
Kligman Maximization	Non-sensitizing (0% sensitization)
Primary Dermal Irritation	Non-irritant (PDII = 0)
Agarose Diffusion Cytotoxicity	No cytopathic effects (grade 0)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2000

Mr. Mark E. Dillon
President
Bio Med Sciences, Inc.
1111 Hamilton Street
Allentown, Pennsylvania 18101

Re: K002109
Trade Name: Oleeva™ Foam
Regulatory Class: Unclassified
Product Code: MDA
Dated: July 10, 2000
Received: July 12, 2000

Dear Mr. Dillon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002109

III. INDICATIONS FOR USE

Oleeva Foam is indicated for the management of hypertrophic scars and keloids. Oleeva Foam may be useful as a prophylaxis after surgical or traumatic dermal injury to aid in the prevention of hypertrophic scars and keloids.

Donna R. Vochmer

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002109